UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION V

DATE: MAY 30 1991

SUBJECT: Review of the Draft Quality Assurance Project Plan for the ATSDR Tri-State Environmental/Blood-Metal Study

FROM: Pat Van Leeuwen, Toxicologist PVL
Technical Support Unit

TO: Glenn Curtis
SPFD, Region VII

I was disappointed to receive the package provided for review by Billy Fairless, Director ENSV, Region VII. This protocol is, for the most-part, non-specific and incomplete and in many sections contains language detrimental to our Superfund initiatives. The comments contained here reflect my specific concerns and those of Brad Bradley, RPM, Region V. Our overall conclusion is that Region V cannot use this QAPP. I think that it is important to bear in mind that if this is to be a combined ATSDR study, different protocols cannot be used in the two Regions as Billy has suggested.

A. Memorandum

1. To my understanding, the purpose of the ATSDR Study is as stated "to examine the interdependence between environmental contaminant sources, behavior, and socioeconomic factors which may influence blood lead levels in susceptible populations more completely". The last sentence in paragraph one of the memorandum states that the study "should be able to establish whether or not the Superfund site is a significant contributor to any elevated blood metal levels". This is not a goal of the ATSDR Study, and while the study may be used by Region VII to accomplish other goals, inclusion of such an interpretation of the ATSDR study goals is inaccurate and unacceptable.

2. Region V does not believe that a correlation between blood and environmental samples can be made if the collection of environmental samples is delayed until the blood-metal data is available. Both environmental and blood measurements represent a snap-shot in time in constantly changing

media. All levels can be expected to change in 90 days. If environmental sampling is to be delayed, blood sampling and analysis would have to be repeated; this is an costly and invasive process and it not likely that parents will submit their children to needless sampling.

3. How can a correlation between any environmental media and blood levels be demonstrated if only children with elevated blood levels are examined? This will produce only a portion of the curve, and will not indicate the extent that behavior and socioeconomics play in this correlation - a stated goal of the ATSDR Study.

4. Billy states that he believes that 400 samples (including background samples) will be sufficient for this study. We believe that such a determination should be based on statistical analysis, and encourage the submission of the protocols to ATSDR or outside statisticians (Alan Marcus, Battelle, is familiar with lead measurement data) before Region V gives their approval for such limited data collection.

5. One cannot expect to merge data that is generated using two different sampling and analysis strategies. If such were the case, data from blood lead studies that have been done at all Superfund sites could be merged to answer these questions. Region VII should realize that if they use one QAPP and Region V uses another, the conclusion may reflect the differences in methodology rather than difference in site exposure.

B. Quality Assurance Project Plan

1. Project Description

Paragraph one: NO single study can ever hope to establish a "cause/effect" relationship. At best we can hope for a significant association. What is meant by "the resulting environmental data will be extrapolated to environmental sources not included in the study area"?

Page 3, objective 3: How can one snap-shot sample in time determine "the extent to which exposure has occurred in populations....."? Maybe it can reflect the blood metal burden of these population at that time point at best.

Page 3 and 4, participation objectives: Collection of samples in a biased manner will only result in a biased study, whose conclusions will have no validity. Region V will not collect their samples in this manner. The USEPA blood lead level of concern is 10 ug/dl, not 25 ug/dl as stated here. Region V will consider this level to be their cut-point for concern over adverse health effects.

2. II Project Organization/Responsibilities

Section h: It is important to USEPA that we have access to the study data to allow further evaluation and refinement of the Lead Uptake/Biokinetic Model. This section needs to be clarified to indicate that EPA may have this data upon request.

3. III Data Quality Objectives

Paragraph two: The assumptions listed here are not valid, and as such, are unacceptable to Region V.

Paragraph three: Region V cannot use this protocol assumption. The true GSD (Geometric Standard Deviation) of the blood lead distribution cannot be known until the blood data is analyzed. Also, it is unlikely that 10% of the children will exhibit blood lead levels greater than 25 ug/dl at any point in time. The Lead Uptake/Biokinetic Model predicts that only 5% of the children will have blood lead levels greater than 10 ug/dl at soil lead levels of 500 ppm, using standard exposure parameter values. Third, a true correlation between any environmental medium and blood metal level cannot be determined if only the elevated blood samples are chosen for correlation.

Page 7, E: The Action Level for lead in drinking water is 15 ug/L.

4. Section IV. Sampling Protocols

Section 1a: Region V will not use a biased sampling method for environmental samples.

Section 1b: The USEPA action level is 10 ug/dl lead in blood.

Page 9. B: Biological and environmental samples must be collected at the same point in time.

Page 10, Section 3, Sample Collection Procedures

In general, the procedures described in this section are sketchy at best and do not fully describe the methodology to be employed in the study. Detailed sampling protocols used in the Tri-City Lead Demonstration Project and for Superfund Blood Lead Studies were submitted to Region VII. We believe that this level of detail should be provided in any good quality assurance plan.

Section a, Drinking Water Samples: The collection of water samples "after the tap is allowed to run for five minutes" was discussed at the Kansas City meeting and found to be unacceptible. This sampling protocol will not result in the "underestimation" of the total lead exposure as suggested; it will eliminate the water exposure component. "Noisy" first-draw data is exposure-specific data and meets the EPA guidelines for

collection of water samples for lead analysis as outlined in the National Primary Drinking Water Regulations for Lead and Copper, May 7, 1991: "First flush tap water samples must stand motionless for at least six hours before the sample is collected". Sample containers, storage and stabilization should be given here or the SOP modified to reflect only metal analysis requirements. It is inappropriate to include SOPs which describe container selection for PCBs, etc. when the only contaminants of interest are cadmiun and lead.

Section b, Indoor House Dust Samples: The collection of dust samples is rather difficult and "tried" protocols were provided for this medium. The protocol given here leaves many questions unanswered: What equipment is to be used? How is the equipment to be used in the actual collection? How many samples can be collected on a single charge? How much dust will be collected? Will pre-weighed glass fiber filters be used to allow weighing of samples for calculation of dust loading?

Section c, Paint Samples: Will a standard area be sampled if peeling, chipped or cracked paint is detected? What is the size of that standard sampling ares?

Section d. Play Area Soil: The protocol states that a "representative" number of play area locations will be sampled; the sampling patterns for small, medium and large areas need to be defined and described and the number of samples to be collected within that area to produce a composite sample should be specified. The description of the three to six inch core is misleading; only the top two centimeters of the sample should be used in the composite sampling. The dilution of surface soil (the soil that adheres to hands clothes, shoes and pets) concentration by addition of large quantities of material that is not readily mobile will result in an incorrect correlation for lead. How will the corer be cleaned? How will field blanks be taken?

5. Section VI. Analytical Methodology

Standardized SOPs are not appropriate for this study and study-specific protocols should be included. No standard SOPs are available for some media of interest - i.e., hand-wipe samples, paint. This protocol should incorporate the recommended Lead-specific protocols provided to the greatest extent possible. It is desireable that data collected in this study will be compatable with Agency lead data collection and analysis strategies, to allow further use of the data for Agency evaluation and refining of the EPA Lead Model.

6. Attachment 2 Sample Containers

This table is mostly useless. Include under sampling protocol the containers to be used, unless you intend to collect data on all these parameters.

SOP No 2130.4A Sample Containers

Include contaminant and medium specific information under the sampling protocols; reference this SOP. Just including this SOP does not say anything about what was done in this study.

If you or Billy have any questions on Region V's concerns over protocol methodology or need additional information during the preparation of this protocol, please feel free to call me at (312) 886-4904.

cc. Brad Bradley, Reg V
Louise Fabinski, ATSDR
Steve Siegel, Reg V
Dave Ullrich, Reg V